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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/673,617

01/25/2001

Kim Sorensen

030307/0191

2002

22428

7590

07/13/2005

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,617

Applicant(s)

SORENSEN ET AL.

Examiner

Michael D. Burkhardt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 9-14, 16, 17, 22-25, 28, 29, 31-33, 35-38 and 40-42 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 8, 15, 18-21, 26, 27, 30, 34 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

5-00

DETAILED ACTION

Priority

It is noted applicants have submitted certified copies of the priority documents to the International Bureau. Attempts are being made to determine if copies of these certified copies have been received by the USPTO.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants present no arguments regarding this rejection as applied to new claim 41 and amended claims 2 and 3. Claim 41 merely repeats the basis for the original rejection (i.e. the language removed from claim 1).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 35 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Claim 1 was rejected for being vague and indefinite due to the phrase "consisting essentially of lactic acid bacterial DNA". The metes and bounds of the claimed subject matter are unclear, because it cannot be determined what characteristics of the claimed vector could be altered and still satisfy the limitation of "consisting essentially of" lactic acid bacterial DNA. The language has been removed from claim 1 and repeated in new claim 42.

Claim 35 provides for the use of a recombinant vector as a starter culture, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Applicants have not amended the claim to include any active process steps, but merely have amended the claim from a method claim to a "Use" claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 35 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e.,

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results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Applicants have not amended the claim to include any active process steps, but merely have amended the claim from a method claim to a "Use" claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 9-14, 16, 17, 22-25, 28-29, 31-33, 36-38, 40 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Dickely et al (Mol. Micro. 1995). This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Upon further consideration, claims 17, 25, 37, 38 and 40 have been included in the rejection.

This is not due to amendment of the claims, and therefore this is a new rejection. Claim 17 reads on rejected subject matter, i.e. a gene product, which may be any of those listed in claim 17.

Dickely et al teach the introduction of a lysine aminopeptidase into the pFG1 vector (see page 843, paragraph bridging first and second columns). Claims 25, 37, and 38 read on rejected subject matter (lactic acid bacterium) that may be auxotrophic, which may be due to a mutation in a gene involved in nucleotide synthesis. Dickely et al teach suppressible auxotrophic

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nonsense mutants of *L. lactis* MG1383 defective in purine (i.e., nucleotide) synthesis (see abstract and page 842, first column, last two paragraphs). Claim 40 reads on subject matter (the method of claim 36), in which the particular environment may be any of those listed in claim 40. Dickely et al teach the use of milk as an environment in which to grow the nonsense mutant bacteria DN209 (page 843, first column, third paragraph).

Applicants argue that Dickely et al teach vectors (pAK89 and pAK89.1) that include an antibiotic resistance gene and DNA from *E. Coli*, and therefore these vectors cannot read on the instant claims. Applicants argue that the present system is distinguished over the art because it is "stably maintained", "useful" in any industrial lactic acid bacterial strain, and does not cause growth inhibition. Applicants also argue the art taught away from use of an amber rather than ochre suppressor.

Applicant's arguments filed 4/21/2005 have been fully considered but they are not persuasive. In contrast to applicant's assertions, Dickely et al do teach a vector lacking an antibiotic resistance gene and *E. Coli* DNA, (see pFG1, Fig. 4 on page 843). The pFG1 vector was maintained in milk cultures of *L. lactis* for 40 generations (p. 843, first column, third paragraph) and is therefore considered "stable" and "useful". Regarding arguments that the Dickely et al vectors are not useful in any industrial lactic acid bacteria and cause growth inhibition, applicants are reminded these are not limitations found in the instant claims. Furthermore, there is no evidence or suggestion by Dickely et al that the vector causes growth inhibition and Dickely et al do not teach away from the use of an amber rather than an ochre suppressor.

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Allowable Subject Matter

Claims 5-6, 8, 15, 18-21, 26, 27, 30, 34, and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhardt whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhardt
Examiner
Art Unit 1633

**CELIAN QIAN
PATENT EXAMINER**

